UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,350	12/29/2000	Stephen M. Coutts	252312005706	1391

25226 7590 03/24/2005

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
HUYNH, PHUONG N	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,350	COUTTS ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-52* is/are pending in the application.

4a) Of the above claim(s) *28, 36, 39-41, 44, 45 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-27,29-35,37,38,42,43,46 and 48-51* is/are rejected.

7)☒ Claim(s) *52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/17/04; 8/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 22-52 are pending.

2. Claims 28, 36, 39-41, 44, 45 and 47 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.

3. Claims 22-27, 29-35, 37-38, 42-43, 46, and 48-52 are being acted upon in this Office Action.

4. The references "privileged & confidential" on PTO 1449, filed 12/17/04 have been crossed out because they are in a Table format, some columns are not legible and they are not cited on PTO 1449.

5. The reference 17 on PTO 1449 filed 8/23/04 has been crossed out because European Office Action is inappropriate to be printed on an issued patent.

6. Applicants maintain the traversal of remaining restriction requirements that US Pat 5,268,454 and 6,060,056 which have claims to conjugates having analog molecules similar to those of the pending claims. Generic claim 22 links all pending claims 22, 48, 49 and 50 are linked as product, process of using and process of making. Every case is examined on its own merit. However, the Examiner will reconsider the restriction requirement upon refiling.

7. In view of the amendment filed 12/16/04, the following rejections remain.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 22-27, 29-35, 37-38, 42-43 and 46 stand rejected under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,060,056 (filed Feb 1991; PTO 892).

The '056 patent teaches a composition for inducing specific B cell anergy to a T cell dependent immunogen such as allergen implicated in an antibody-mediated pathology comprising a plurality of conjugate wherein the conjugate comprises at least two analog of immunogen such as melittins peptide that lack T cell epitopes and chemically conjugated to a valency platform molecule such as homogenous polymer polyethylene glycol comprises branching group that contains a specific number of attachment sites (See entire document, Figure 11 of '056 patent, claims 1-15, in particular). The reference composition wherein the branching group is diamino acid, i.e, ethylenediamin (See Figure 11, col. 6, line 15, in particular). The reference composition wherein the analog molecules are the same class (See claim 6 of '056 patent, in particular). The reference composition wherein the conjugates comprises 3-5 analog molecules (See col. 29, in particular). The term "comprising" is open-ended. It expands the claimed conjugates of four analog molecules to include the reference conjugates that comprise 5 analog molecules. The reference composition comprises a pharmaceutically acceptable carrier for injection (See claim 15 of '056 patent, col. 6, lines 34, in particular). The reference valency platform molecules are substantially non-immunogenic (See abstract, in particular) and comprises polyethylene glycol having the formula CH2(CH2OCH2)rCH2 wherein r is 74 which is within r =0 to 300 (See col. 5, lines 51-67, Figure 11, in particular). The reference immunogen melittin peptides are allergen and are also external immunogen. Claim 35 is included in this rejection because the term "comprises" is open-ended. It expands the triethylene glycol to include the reference's multiple units of ethylene glycol. Thus, the reference teachings anticipate the claimed invention.

Applicants' arguments filed 12/16/04 have been fully considered but are not found persuasive.

Applicants' position is that applicants are in the process of contacting the necessary persons and the appropriate paperwork will be submitted once all of the necessary signatures have been obtained. The actual inventorship for the current apolication is Stephen Coutts, David Jones, Paul Barstad, Michael Iverson and Lin Yu. Lin Yu's contribution to the claimed subject matter is soley to conjugates where the branching groups are derived from triamine and he is therefore a joint inventor with respect to claim 52 only.

In response, the rejection is maintained because a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent. Until

the appropriate paperwork and signatures have been submitted to the office, the rejection is maintained for the reason of record.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 22-27, 29-35, 37-38, 42-43, 46, and 48-51 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 7, 9, 10, 12, 13, 14, 15, 16, 17 and 18 of U.S. Patent No. 6,060,056. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 15 of the '056 patent recites a pharmaceutical composition comprising a therapeutic effective amount of the conjugate for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology comprising a non-immunogenic valency platform molecule and at least two analog molecules of the immunogen wherein (a) the analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and (b the conjugate lacks T cell epitopes capable of activity T cells in said individual, and further wherein the analog molecules are selected from the group consisting of peptides, polypeptides, proteins, glycoproteins, lipoproteins, carbohydrates, lipids, and lipopolysaccharides (genus).

Although the pending claim 22 of instant application recites a composition for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated

pathology comprising a plurality of a conjugates, wherein the conjugate comprises: at least two analog molecules of the immunogen conjugated to a chemically defined valency platform molecule, wherein said analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and wherein the analog molecules lack T cell epitopes; wherein the chemically defined valency platform molecule comprises branching groups, and wherein the valency platform molecule contains a specific number of attachment sites whereby the valency of said platform molecule is defined and wherein the molecular weight of the valency platform molecules is substantially homogenous and wherein the valency platform molecules have attachment sites at the same location (species), the composition of the '056 patent (genus) would include the composition of instant application (Species). The issuance of a patent to claims 22, 23, 25, 33, 34 and 35 of instant application would anticipate the composition of the '056 patent because the specific chemically defined valency platform molecule comprises branching groups (species) conjugated to analog molecules in claim 22 of instant application anticipates the composition comprising the generic valency platform molecule conjugated to analog molecules of the '056 patent. Further, the valency platform molecule such as polyethylene glycol in instant claims 31-32 is the same as that of claim 10, 12 and 13 of the '056 patent having branch groups such as D-lysine residues (see col. 6, line 26 of '056 patent).

Claim 16 of '056 patent recites a method of inducing specific B cell anergy to a T cell-dependent immunogen in an individual comprising administering to the individual an effective amount of the pharmaceutical composition comprising the of the conjugate for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology comprising a non-immunogenic valency platform molecule and at least two analog molecules of the immunogen wherein (a) the analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and (b the conjugate lacks T cell epitopes capable of activity T cells in said individual, and further wherein the analog molecules are selected from the group consisting of peptides, polypeptides, proteins, glycoproteins, lipoproteins, carbohydrates, lipids, and lipopolysaccharides (genus) and a pharmaceutically acceptable carrier. Claim 48 of instant application recites a method of inducing specific B cell anergy to a T cell-dependent immunogen in an individual comprising administering to the individual an effective amount of the composition comprising a plurality of a conjugates, wherein the conjugate comprises: at least two analog molecules of the immunogen conjugated to a chemically defined valency platform molecule, wherein said analog molecules bind specifically

to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and wherein the analog molecules lack T cell epitopes; wherein the chemically defined valency platform molecule comprises branching groups, and wherein the valency platform molecule contains a specific number of attachment sites whereby the valency of said platform molecule is defined and wherein the molecular weight of the valency platform molecules is substantially homogenous and wherein the valency platform molecules have attachment sites at the same location (species). The issuance of a patent to claim 48 of instant application (species) would anticipate the method of inducing specific B cell anergy using the genus composition of the '056 patent.

Claim 17 of '056 patent recites a method of treating an individual for an antibody mediated pathology in which undesired antibodies are produced in response to a T cell-dependent immunogen comprising administering to the individual an effective amount of the pharmaceutical composition comprising the of the conjugate for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology comprising a non-immunogenic valency platform molecule and at least two analog molecules of the immunogen wherein (a) the analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and (b the conjugate lacks T cell epitopes capable of activity T cells in said individual, and further wherein the analog molecules are selected from the group consisting of peptides, polypeptides, proteins, glycoproteins, lipoproteins, carbohydrates, lipids, and lipopolysaccharides (genus) and a pharmaceutically acceptable carrier. Claim 49 of instant application recites a method of treating an individual for an antibody mediated pathology in which undesired antibodies are produced in response to a T cell-dependent immunogen comprising administering to the individual an effective amount of the comprising a plurality of a conjugates, wherein the conjugate comprises: at least two analog molecules of the immunogen conjugated to a chemically defined valency platform molecule, wherein said analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and wherein the analog molecules lack T cell epitopes; wherein the chemically defined valency platform molecule comprises branching groups, and wherein the valency platform molecule contains a specific number of attachment sites whereby the valency of said platform molecule is defined and wherein the molecular weight of the valency platform molecules is substantially homogenous and wherein the valency platform molecules have attachment sites at the same location (species). The issuance of a patent to claim 49 of instant

application (species) would anticipate the method of treating using the genus composition of the '056 patent.

Claim 18 of the '056 patent recites a method making the composition comprising a therapeutic effective amount of the conjugate for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology comprising a non-immunogenic valency platform molecule and at least two analog molecules of the immunogen wherein (a) the analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and (b the conjugate lacks T cell epitopes capable of activity T cells in said individual, and further wherein the analog molecules are selected from the group consisting of peptides, polypeptides, proteins, glycoproteins, lipoproteins, carbohydrates, lipids, and lipopolysaccharides (genus). Claim 50 of instant application recites a method making the composition for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology comprising a plurality of a conjugates, wherein the conjugate comprises: at least two analog molecules of the immunogen conjugated to a chemically defined valency platform molecule, wherein said analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and wherein the analog molecules lack T cell epitopes; wherein the chemically defined valency platform molecule comprises branching groups, and wherein the valency platform molecule contains a specific number of attachment sites whereby the valency of said platform molecule is defined and wherein the molecular weight of the valency platform molecules is substantially homogenous and wherein the valency platform molecules have attachment sites at the same location (species), the composition of the '056 patent (genus) would include the composition of instant application (Species). Claim 51 of instant application recites a method making the composition of claim 29, the method comprising combining the conjugates with a pharmaceutically acceptable carrier. The issuance of a patent to claims 50-51 of instant application (species) would anticipate the method of making the genus composition of the '056 patent.

Applicants' arguments filed 12/16/04 have been fully considered but are not found persuasive.

Applicants' position is that applicants believe the pending claims are patentably distinct from the claims of US Pat 6,060,056. No reason has been provided as to why a person of

ordinary skill in the art would conclude that invention of the pending claims is an obvious variation of the invention defined in the claims of US Pat 6,060,056.

In contrast to applicants' assertion that no reason has been provided as to why a person of ordinary skill in the art would conclude that invention of the pending claims is an obvious variation of the invention defined in the claims of US Pat 6,060,056, species of conjugate in the instant application anticipates the generic conjugate of the '056 patent. Applicants are referred to the detailed explanation above.

12. Claim 52 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

16. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
March 18, 2005

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600